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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/07/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,483

Applicant(s)

SUKHATME, VIKAS P.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-35,37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,10-13,18-21,24,27-35,37 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8,9,14-17,22,23,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other.

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DETAILED ACTION

Claims 1-35, 37 and 39 are pending in the present application. Claims 1-4, 6, 8, 9, 14-17, 22, 23, 25 and 26 are under examination.

Response to Amendment

The rejection of claims 1-4, 8, 9, 14-16, 22 and 25 under 35 U.S.C. 102(e) as being anticipated by Davidson (US Patent No. 6,057,122) has been withdrawn in view of Applicant's Amendment filed 25 February 2002.

The rejection of claims 6 and 17 under 35 U.S.C. 103(a) as being unpatentable over Davidson has been withdrawn in view of Applicant's Amendment filed 25 February 2002.

The rejection of claims 23, 26, 36 and 38 under 35 U.S.C. 103(a) as being unpatentable over either O'Reilly et al. (WO 97/15666) (O'Reilly) or Hägg et al. (Genomics Vol.45 1997) (hereinafter "Hägg") in view of Davidson has been withdrawn in view of Applicant's Amendment filed 25 February 2002.

The rejection of claims 3, 14-17, 22, 23, 25, 26, 36 and 38 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention has been withdrawn in view of Applicant's Amendment filed 25 February 2002.

The rejection of claims 1-4, 6, 8, 9, 14-17, 22, 23, 25, 26, 36 and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention has been withdrawn in view of Applicant's Amendment filed 25 February 2002.

Claims 1-4, 6, 8, 9, 14-17, 22, 23, 25, 26, 36 and 38 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention for the reasons of record set forth in the office action mailed 2 August 2002.

Response to Arguments

Claims 1-4, 6, 8, 9, 14-17, 22, 23, 25, 26, 36 and 38 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention for the reasons of record set forth in the office action mailed 2 August 2002. Applicant's arguments filed 25 February 2002 have been fully considered but they are not persuasive.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . . [emphasis added]." The written description requirement has been well established and characterized in the case law. According the written description requirement, a specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cuth v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he was in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."

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See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

As discussed in the office action mailed 2 August 2001, Applicant's invention is drawn to a method of making a restin protein or a "biologically active mutant, fragment, derivative or fusion protein thereof." The claimed biologically active mutants, fragments, derivatives or fusion proteins of restin have not been adequately described in the specification such that one of skill in the art would reasonably conclude that Applicant was in possession of such a broad genus of compounds at the time the invention was made.

Applicant cites the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶1, 'Written Description' Requirement" MPEP 2163, for the presumption "that an adequate written description of the claimed invention is present in the specification as filed" and thus the "rejection of an original claim for lack of written description should be rare."

Although, the guidelines state a written description rejection should be rare, they do not preclude the rejection in the instant case where Applicant has failed to teach a representative number of species of mutants, fragments, derivatives or fusion proteins of restin such that one of skill in the art would conclude that Applicant was in possession of these molecules.

Applicant relies upon the disclosure of apomigren, which is fragment of full length restin comprising about the last 85 amino acid residues of restin and upon the disclosure of methods of cloning and assaying for apomigren. Applicant asserts that this disclosure alone is sufficient to describe the broad genus recited by the claims. Although Applicant has adequately described apomigren and possibly fragments comprising the 85 amino acids of apomigrin, the claims read on sequences that include the first 97 amino acids of restin. Applicant's disclosure of apomigren

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clearly does not describe any biologically active mutants, fragments, derivatives or fusion proteins of restin that include the first 97 amino acids of the molecule nor has Applicant described functional mutants, fragments, derivatives or fusion proteins of the approximately 85 amino acids of apomigrin. Applicant asserts with respect to the apomigren sequence that:

Apomigren is a subsequence of full-length restin, and apomigren possesses the anti-angiogenic activity of full length restin, and apomigren possesses the anti-angiogenic activity of full-length restin. One of ordinary skill would therefore understand that the region responsible for the anti-angiogenic activity is somewhere within the region making up the apomigren sequence.

First, it should be noted that the scope of the claims is well beyond the scope of apomigren.

Second, Applicant has done little more than disclose apomigren and send the skilled artisan on a hunt for mutants, fragments, derivatives or fusion proteins of apomigren having anti-angiogenic activity. The guidelines as set forth in MPEP 2163 (I)(A) state:

A biomolecule described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method for obtaining the claimed sequence.

By stating that the "activity is somewhere within the region making up the apomigren sequence,"

Applicant admits that no known correlation exists between the mutants, fragments and variants of the sequence claimed and the anti-angiogenic activity. The court in *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 also address this issue explicitly stating:

A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. . . . It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

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Applicant has taught apomigren and an assay for anti-angiogenic activity. Therefore, even though Applicant teaches a sequence and a method for assaying for anti-angiogenic activity, it is still insufficient to describe the broad genus claimed. Applicant must show some common structural feature of either the apomigren sequence or the entire restin sequence that would allow one of skill in the art to visualize the broad genus claimed.

On page 18 of the Amendment, Applicant has erroneously interpreted the present rejection to require that Applicant teach all methods of altering amino acid sequences including methods of truncating sequences, making deletion mutations and site-directed mutagenesis. This interpretation is misguided. The present rejection does not require Applicant teach how to make the biologically active mutants, fragments, derivatives or fusion proteins of restin. Rather, the written description rejection requires that Applicant at least teach regions, consensus sequences or motifs required for the the anti-angiogenic activity of the sequences such that one of skill in the art would appreciate that Applicant actually invented or had possession of that which is claimed.

For the foregoing reasons, claims 1-4, 6, 8, 9, 14-17, 22, 23, 25, 26, 36 and 38 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
April 29, 2002


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